

dated October 29, 1990, advised the Patent and Trademark Office that the animal drug product had undergone a regulatory review period. The letter also stated that the active ingredient, oxfendazole, represented the first permitted commercial marketing for use in a food animal. Shortly thereafter, the PTO requested that the FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Synanthic® is 6,022 days. Of this time, 4,812 days occurred during the testing phase of the regulatory review period, while 1,210 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act became effective:* March 25, 1974. The applicant claims August 8, 1975 as the date the investigational new animal drug (INAD) application became effective. However, FDA records indicate that the date of FDA's official acknowledgment letter assigning a number to the INAD was March 25, 1974, which is considered to be the effective date for the INAD.

2. *The date the application was initially submitted with respect to the animal drug product under section 512(b) of the Federal Food, Drug, and Cosmetic Act:* May 27, 1987. The applicant claims May 22, 1987, as the date the new animal drug application (NADA) was filed. However, a review of FDA records reveals that the date of FDA's official acknowledgment letter assigning a number to the NADA was May 27, 1987, which is considered to be the submission date for the NADA.

3. *The date the application was approved:* September 17, 1990. FDA has verified the applicant's claim that NADA 140-854 was approved on September 17, 1990.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 3 years of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before February 19, 1991, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before June 18, 1991, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review

period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d Sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 11, 1990.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 90-29749 Filed 12-19-90; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 90N-0438]

**Drug Export; Macrobid®
(Nitrofurantoin Modified-Release/
Nepi) Capsules**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Norwich Eaton Pharmaceuticals, Inc. has filed an application requesting approval for the export of the human drug Macrobid® (nitrofurantoin modified-release/nepi) Capsules to Canada.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT:

Frank R. Fazzari, Division of Drug Labeling Compliance (HFD-313), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8073.

SUPPLEMENTARY INFORMATION: The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of drugs that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an

application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the Federal Register within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that Norwich Eaton Pharmaceuticals, A Procter & Gamble Co., P.O. Box 191, Norwich, NY 13815-0191, has filed an application requesting approval for the export of the drug Macrobid® (nitrofurantoin modified-release/NEPI) Capsules, to Canada. The application was received and filed in the Center for Drug Evaluation and Research on November 9, 1990, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by December 31, 1990, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Drug Evaluation and Research (21 CFR 5.44).

Dated: December 6, 1990.

Daniel L. Michels,

Director, Office of Compliance, Center for Drug Evaluation and Research.

[FR Doc. 90-29831 Filed 12-19-90; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 90E-0343]

**Determination of Regulatory Review
Period for Purposes of Patent
Extension; Exosurf® Neonatal™**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Exosurf[®] Neonatal[™] and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, room 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Nancy Pirt, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Exosurf[®]

Neonatal[™]. Exosurf[®] Neonatal[™] (colfosceril palmitate, cetyl alcohol, tyloxapol) is indicated for: (1) Prophylactic treatment of infants with birth weights of less than 1,350 grams (g) who are at risk of developing respiratory distress syndrome; (2) prophylactic treatment of infants with birth weights greater than 1,350 g who have evidence of pulmonary immaturity; and, (3) rescue treatment of infants who have developed respiratory distress syndrome. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Exosurf[®] Neonatal[™] (U.S. Patent No. 4,312,860) from Burroughs Wellcome Co., and requested FDA's assistance in determining this patent's eligibility for patent term restoration. FDA, in a letter dated November 2, 1990, advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period. The letter also stated that the active ingredient, colfosceril palmitate, represented the first permitted commercial marketing or use, but it was not the first commercial marketing or use of the active ingredients cetyl alcohol or tyloxapol. Shortly thereafter, the patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Exosurf[®] Neonatal[™] is 1,891 days. Of this time, 1,723 days occurred during the testing phase of the regulatory review period, while 168 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective:* May 31, 1985. FDA has verified the applicant's claim that the date the investigational new drug application became effective was May 31, 1985.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* February 18, 1990. FDA has verified the applicant's claim that the new drug application (NDA) for Exosurf[®] Neonatal[™] (NDA 20-044) was filed on February 18, 1990.

3. *The date the application was approved:* August 2, 1990. FDA has verified the applicant's claim that NDA 20-044 was approved on August 2, 1990.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations

of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,029 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before February 19, 1991, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before June 18, 1991, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d Sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

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Dated: December 11, 1990.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 90-29748 Filed 12-19-90; 8:45 am]

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Health Resources and Services Administration

Filing of Annual Report of Federal Advisory Committee

Notice is hereby given that pursuant to section 13 of Public Law 92-463, the Annual Report for the following Health Resources and Service Administration's Federal Advisory Committee has been filed with the Library of Congress:

National Advisory Council on the National Health Service Corps

Copies are available to the public for inspection at the Library of Congress Newspaper and Current Periodical Reading room, room 1026, Thomas Jefferson Building, Second Street and Independence Avenue, SE., Washington, DC, or weekdays between 9 a.m. and 4:30 p.m. at the Department of Health and Human Services, Department Law Library, HHS North Building, room G-619, 330 Independence Avenue, SW., Washington, DC, telephone (202) 245-6791. Copies may be obtained from: Anna Mae Voigt, National Advisory Council on the National Health Service